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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,785	12/20/2000	William J. Curatolo	PC10755AJTJ	8464

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/742,785	CURATOLO ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/24/05 & 4/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-15, 18-44, 47-72, 75-92, 95-102, 104-112, 115-122, 124-132 and 135-145 and 156-161
Continuation of Disposition of Claims: Claims withdrawn from consideration are 3-11, 19-24, 32-40, 48-53, 60-68, 76-81, 88-91, 96-101, 108-111, 116-121, 128-131 and 136-141

Continuation of Disposition of Claims: Claims rejected are 1,2,12-15,18,25-31,41-44,47,54-59,69-72,75,82-87,92,95,102,104-107,112,115,122,124-127,132,135,142-145 and 156-161.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, amendment, remarks and request for extension of time, all filed 3/13/07; and IDS filed 4/05/07 and 1/24/07. Claims 1-15, 18-44, 47-72, 75-92, 95-102, 104-112, 115-122, 124-132 and 135-145 and 156-161 are pending. Claims 3-11, 19-24, 32-40, 48-53, 60-68, 76-81, 88-91, 96-101, 108-111, 116-121, 128-131 and 136-141 are withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/13/2007 has been entered.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 12-15, 18, 25-31, 41-44, 54-59, 69-72, 75, 82-87, 92, 95, 102, 104-107, 112, 115, 122, 124-127, 132, 135 and 142-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyajima et al. (US 4,983,593).

4. Miyajima discloses a composition that comprises 5-(5,5-dimethyl-1,3,2-dioxaphosphorinane-2-yl)-1,4-dihydro-2,6-dimethyl-4- (3- itrophenyl)-3-pyridine carboxylic acid 2-(phenylmethyl)amino) ethyl ester P-oxide hydrochloride-thanol (NZ-105) and hydroxypropylmethylcellulose acetate succinate ("HPMCAS") and the composition can be mixed with fillers (sugars, e.g. lactose, sucrose, etc., glycitols, e.g. mannitol, sorbitol, xylitol, etc., starches, e.g. corn starch, potato starch, wheat starch, rice starch, etc., crystalline cellulose, inorganic salts, e.g. calcium hydrogen phosphate anhydride, synthetic aluminum silicate) or disintegrants, binders, lubricants or other additives (abstract; column 2, lines 34-40; column 4, lines 16-46; and Examples 1-6). Miyajima's composition also contains urea or surface active agents (column 4, line 49) and is prepared by dissolving NZ-105 and HPMCAS in an organic solvent, removing the solvent by freeze drying, spray drying or vacuum drying (column 3, lines 55-65). NZ-105 is a drug and HPMCAS meets the limitation of the concentration-enhancing polymer since HPMCAS is one of the concentration enhancing polymers recited in the instant claims. Tablets and capsules are orally administered dosage forms,

According to paragraphs [0024], [0025] and [0026] of the published application, "solubility-improved form" is a "form of the drug which has increased solubility relative to the

least soluble form of the drug known. Thus, the term implies that a less soluble form of the drug exists and is either known or has been determined, i.e., known, for example, from the scientific or patent literature, or determined by or otherwise known to the investigator. A "solubility-improved form" may consist of a **highly soluble form of the drug alone**, may be a composition comprising a **highly soluble form of the drug plus inert excipients**, or may be a composition comprising the drug in **a poorly or highly soluble form and one or more excipients which have the effect of increasing the solubility of the drug,** regardless of the length of time for which the solubility is increased. Examples of "solubility-improved forms" include but are not limited to: (1) a crystalline highly soluble form of the drug **such as a salt**; (2) a high-energy crystalline form of the drug; (3) a hydrate or solvate crystalline form of a drug; (4) an amorphous form of a drug (for a drug that may exist as either amorphous or crystalline); (5) a mixture of the drug (amorphous or crystalline) and a solubilizing agent; or (6) a solution of the drug dissolved in an aqueous or organic liquid."

"Alternatively, the term "solubility-improved form" refers to a form of the drug alone or in a composition as is described above that, when delivered to an in vivo environment of use (such as, for example, the gastrointestinal tract of a mammal) or a physiologically relevant in vitro solution (such as phosphate buffered saline or a Model Fasted Duodenal solution described below) provides, or is capable of providing, at least temporarily, a concentration of drug that is at least 1.25-fold the equilibrium concentration of drug in the use environment."

"A solubility-improved form of a drug is one that meets at least one of the above definitions." Thus, by the definition for "solubility-improved form or a drug," the NZ-105 of Miyajima meets the limitation of "solubility-improved form of a drug."

While Miyajima does not describe HPMCAS as a concentration-enhancing polymer, the instant claims recite HPMCAS as one of the concentration enhancing polymers. Aqueous solubility of less than mg/ml is a property of the drug. No specific drug is recited in the instant claims. NZ-105 is a drug that is poorly soluble in water (column 1, lines 37-58). The method claims administer the drug composition. Miyajima also administers the composition.

Response to Arguments

5. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Applicant argues:

a) NZ-105 is crystalline and is not a solubility enhanced form within the scope of the claims because applicant's claims exclude crystalline form; and that Miyajuma does not also disclose a composition of HPMCAS and NZ-105 that is a physical mixture because Miyajima because Miyajima prepares the composition by dissolving the Z-105 and HPMCAS in an organic solvent and removing the solvent by evaporation.

Response:

While NZ-105 of Miyajima may be crystalline, applicant defines a "solubility-improved form" as "form of the drug which has increased solubility relative to the least soluble form of the drug known. Thus, the term implies that a less soluble form of the drug exists and is either known or has been determined, i.e., known, for example, from the scientific or patent literature, or determined by or otherwise known to the investigator. A "solubility-improved form" may consist of a **highly soluble form of the drug alone**, may be a composition comprising a **highly soluble form of the drug plus inert excipients**, or may be a composition comprising the drug in

a poorly or highly soluble form and one or more excipients which have the effect of increasing the solubility of the drug, regardless of the length of time for which the solubility is increased. Examples of "solubility-improved forms" include but are not limited to: (1) a crystalline highly soluble form of the drug **such as a salt**; (2) a high-energy crystalline form of the drug; (3) a hydrate or solvate crystalline form of a drug; (4) an amorphous form of a drug (for a drug that may exist as either amorphous or crystalline); (5) a mixture of the drug (amorphous or crystalline) and a solubilizing agent; or (6) a solution of the drug dissolved in an aqueous or organic liquid."

"Alternatively, the term "solubility-improved form" refers to a form of the drug alone or in a composition as is described above that, when delivered to an in vivo environment of use (such as, for example, the gastrointestinal tract of a mammal) or a physiologically relevant in vitro solution (such as phosphate buffered saline or a Model Fasted Duodenal solution described below) provides, or is capable of providing, at least temporarily, a concentration of drug that is at least 1.25-fold the equilibrium concentration of drug in the use environment." See paragraphs [0024], [0025] and [0026] of the published application. The NZ-105 of Miyajima falls within what applicant terms "solubility-improved form" and therefore, the NZ-105 is within the scope o9f the claims. The solubility of the "solubility-improved from" is a characteristic/property of the drug form and a chemical material/composition/product and its properties are not separable.

Furthermore, applicant describes simple physical mixture as one that is not dispersions; that in a simple physical mixture, the drug has properties that match the properties of the drug alone (paragraphs [0037] and [0040]) and the Miyajima composition meets physical mixture within the scope of the claims. Miyajima does not say that the property of the drug with the

HPMCAS differs from the properties of the drug alone. The claims are product claims and not method claims. No particular drug is claimed while the examples are directed to specific drug

The PTO does not have laboratories where test may be conducted to show differences between compositions so that "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant has not provided factual evidence to show the difference of the claimed composition that is directed to any drug/polymer products from the composition of Miyajima bearing in mind that applicant's description of what "solubility-improved form" of a drug is, reads on the NZ-105 of Miyajima. Thus the description of the Merck Index for NZ-105 does not exclude it from applicant's definition of what a "solubility-improved form" is.

6. Claims 1, 2, 12-15, 18, 25-31, 41-44, 54-59, 69-72, 75 and 82-85 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn (US 4,461,759).

Dunn discloses a composition that comprises a composition that comprises varapamil and acid retardant cellulose derivative (abstract; column 3, lines 6-15) and when cellulose acetate phthalate is the acid retardant, the drug and the cellulose acetate phthalate and/or bulking or disintegrant agent are granulated (column 4, lines 30-35). Varapamil is poorly soluble in water. See also claims 8 and 9. While Dunn does not describe cellulose acetate phthalate as a concentration-enhancing polymer, the instant claims recite cellulose acetate phthalate as one of the concentration enhancing polymers. Aqueous solubility of less than mg/ml is a property of the drug. No specific drug is recited in the instant claims.

While Dunn uses the hydrochloride salt in the examples, it is noted that Dunn states that **verapamil or pharmaceutically acceptable salt** (abstract; column 3, lines 6 and 7) and thus, Dunn specifically contemplates verapamil as well as the pharmaceutically acceptable salt such as the hydrochloride. It is also noted that the claims do not recite any specific solubility except that the claims state a relative solubility. The instant composition comprises ... and the instant claims do not recite a physical mixture and the prior art does not describe a chemical interaction between the drug and the polymer where a covalent or ionic bond is formed.

Response to Arguments

7. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Applicant argues that both verapamil and verapamil hydrochloride are outside the scope of applicant's claims because the claims require that the solubility of the solubility-improved form be "at least 2-fold the solubility of the more soluble of the crystalline hydrochloride salt and the crystalline free base drug form" and that this language excludes the more soluble drug form.

Response:

Specifically, the claims recite no specific drugs except that the drug be "solubility-improved form," which, by applicant's guidance in the instant specification at paragraphs [0024], [0025] and [0026] of the published application, is one that consists of a **highly soluble form of the drug alone**, may be a composition comprising a **highly soluble form of the drug plus inert excipients**, or may be a composition comprising the drug in **a poorly or highly soluble form and one or more excipients which have the effect of increasing the solubility of the drug,** regardless of the length of time for which the solubility is increased. Examples of "solubility-

improved forms" include but are not limited to: (1) a crystalline highly soluble form of the drug **such as a salt**; (2) a high-energy crystalline form of the drug; (3) a hydrate or solvate crystalline form of a drug; (4) an amorphous form of a drug (for a drug that may exist as either amorphous or crystalline); (5) a mixture of the drug (amorphous or crystalline) and a solubilizing agent; or (6) a solution of the drug dissolved in an aqueous or organic liquid. "Alternatively, the term "solubility-improved form" refers to a form of the drug alone or in a composition as is described above that, when delivered to an in vivo environment of use (such as, for example, the gastrointestinal tract of a mammal) or a physiologically relevant in vitro solution (such as phosphate buffered saline or a Model Fasted Duodenal solution described below) provides, or is capable of providing, at least temporarily, a concentration of drug that is at least 1.25-fold the equilibrium concentration of drug in the use environment." Verapamil or verapamil-HCl falls within the scope of what applicant terms "solubility-improved form." If the claimed composition comprising solubility improved form of any drug and any concentration enhancing polymer has 2-fold the solubility of the more soluble form of the drug, it flows that the composition of Dunn comprising verapamil or verapamil-HCl, which fits the description of "solubility-improved form," and concentration enhancing polymer would also have the property of having at least 2 fold the solubility of the most soluble form. Crystalline verapamil hydrochloride or the free base of verapamil (Merck Index) does not violate applicant's definition of what the "solubility-improved form" is as per applicant's specification described above. The PTO is not equipped with laboratories to show differences between compositions and products so that "when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The Merck Index is not a

showing but rather supports verapamil or the verapamil salt as meeting the scope of "solubility-improved form" according to applicant's description of "solubility-improved form."

8. Claims 1, 2, 12-15, 18, 25-31, 41-44, 47, 54-59, 69-72, 75, 82-87, 92, 95, 102, 104-107, 112, 115, 122, 125-127, 132, 135 and 142-145 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 5,496,561).

Okada discloses a controlled release pharmaceutical composition comprising crystalline form of a drug (column 3, line 32); polymer such as hydroxypropylmethylcellulose acetate succinate, hydoxypropylmethylcellulose phthalate, cellulose acetate phthalate and carboxymethylethyl cellulose (column 3, lines 36-39, column 4, lines 20-25); plasticizers such as triethyl citrate, triacetin, polyethylene glycol, castor oil, polysorbitan monooleate, glycerine fatty acid ester (column 5, lines 5-8).

The instant application claims a composition that comprises a drug in a pharmaceutically acceptable solubility-improved form and a concentration-enhancing polymer is a salt and several examples of drugs that are suitable in the instant invention are listed in the specification (page 30, line 31 to page 31 line 5, page 35, line 13 to page 36 line 26 and page 26, line 30 to page 29 line 18). In the instant application, the recitation that the composition achieves a maximum equilibrium concentration of at least 1.25 fold of a drug ... is a property of the drug composition and property of a composition is not separable from the composition; and thus the composition of the prior art would inherently achieve said equilibrium concentration relative to the drug.

Instant claims 25-28, 30, 54-57 and 82 recite the property of the composition and the teaching of Okada meets the limitations of said claims; diclofenac, which is one of the drugs disclosed in Okada has analgesic, anti-inflammatory and antipyretic activities; and thus Okada

meets the limitation of instant claim 29. The method of the instant claims administers the drug and the concentration-enhancing polymer and the prior art teaches administering the composition to a patient/subject in need thereof.

Response to Arguments

9. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Applicant argues that Okada does not disclose a physical mixture of a solubility-improved drug and a polymer because the dosage form in Okada s a structure, and not a physical mixture.

Response:

A mixture reads on mixing a polymer with the core materials in a fluidized bed to coat the core material containing the drug. Okada does not describe the formation of covalent or ionic bond between the drug and the polymer, such a bond formation would not be a physical process.

10. Claims 1, 30, 58, 86, 126 and 156-161 are rejected under 35 U.S.C. 102(e) as being anticipated by Bymaster et al. (US 6,147,072).

Bymaster discloses treating psychosis, acute mania, mild anxiety states or depression by administering to a patient in need thereof a composition that comprises a first component drug selected form olanzapine, clozapine, risperidone, sertindole, quetiapine and ziprasidone, and a second component (abstract; column 1, lines 42-46; column 2, line 9-51; and claim 2), and the composition is formulated as tablets, chewable tablets, capsules, solutions, intranasal sprays or powders, troches, suppositories, transdermal patches and suspensions (column 10, lines 8-12)

and polymers such as hydroxypropyl methylcellulose phthalate and hydroxypropyl methylcellulose acetate succinate are associated with the drug (column 10, lines 61-67).

Response to Arguments

11. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Applicant argues that Bymaster's composition is not a physical mixture of solubility improved form and concentration enhancing polymer.

Response:

A mixture reads on mixing a polymer with the core materials in a fluidized bed to coat the core material containing the drug. Okada does not describe the formation of covalent or ionic bond between the drug and the polymer, such a bond formation would not be a physical process.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 87, 92, 95, 102, 105-107, 112, 115, 122, 124-127, 132, 135 and 142-145 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn (US 4,461,759).

Dunn is discussed above. Dunn discloses a composition where the drug verapamil and cellulose acetate phthalate are granulated. Dunn does not discuss administering the verapamil composition to a subject in need thereof. Verapamil is a cardiovascular drug and the drug composition has to be administered in order for it to provide cardiovascular positive effect in a subject. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cardiovascular composition comprising verapamil. One having ordinary skill in the art would have been motivated to administer the verapamil formulation to a subject in need thereof with the expectation of treating cardiovascular problems such as irregular heartbeats (arrhythmias) and high blood pressure.

Response to Arguments

15. Applicant's arguments filed 3/13/07 have been fully considered but they are not persuasive.

Applicant argues that Dunn is concerned with solving different problem from applicant because Dunn retards the release of verapamil instead of enhancing the concentration, the solubility verapamil hydrochloride is well above the solubility limit of 1 mg/ml of

because that the Merck Index, 12th edition gives the solubility of verapamil hydrochloride at 83 mg/ml in water.

Response:

Applicant recognizes on page 6 of the response that the drug forms of Dunn are verapamil and verapamil pharmaceutically acceptable salt. Thus, by applicant's own admission, Dunn is concerned with verapamil. The 12th edition of the Merck Index, which applicant refers to states that verapamil is practically insoluble in water and this insolubility is less than 1 mg/ml. Claim 1 is directed to composition containing a drug, any drug, in a solubility enhanced or improved form; a drug having an aqueous solubility of less than 1 mg/ml is not in the solubility enhanced form but that the solubility enhanced form is at least 2-fold the solubility of the more soluble of the drug form. Therefore the drug in the claimed composition is not in the form that has a solubility of less than 1 mg/ml. The 83 mg/ml solubility of verapamil HCl in water is a more soluble verapamil than the base verapamil and falls within the scope of the solubility-improved form as defined by applicant. The claims are not directed to method of enhancing the concentration of drug, rather, the claims are directed to composition comprising solubility-improved from which according to applicant encompasses **highly soluble form of the drug alone or** a crystalline highly soluble form of the drug **such as a salt** (see paragraphs [0024], [0025] and [0026] of the published application). Therefore, verapamil hydrochloride is a solubility-improved from falling within the scope of applicant's solubility-improved form as per paragraphs [0024], [0025] and [0026] of the published application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-272-0594.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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